REMARKS.

Upon entry of this Amendment, claims 1-22 are pending. Claims 1-3, 5, 7-9, 11-13 and 22 stand rejected under 35 U.S.C. § 102(e) as anticipated by U.S. Patent Application Publication 2003/0118571 to *Reid et al.* Claims 18-21 stand rejected under 35 U.S.C. §112 ¶ 1 as not being enabled by the specification. Claims 4, 6, 10 and 14-17 are objected to as dependent upon a rejected base claim.

In view of the following remarks, Applicant respectfully submits that claims 1-22 are in condition for allowance because, among other reasons, (1) agar is not a mucopolysaccharide, and (2) by law, the claims are not limited in scope to the preferred embodiment disclosed in the specification.

I. Rejection of Claims 1-3, 5, 7-9, 11-13 and 22 Under §102.

The Examiner claims that *Reid et al.* discloses agar as a prebiotic and that agar is a mucopolysaccharide. In paragraph 46 of *Reid et al.*, however, agar is specifically identified as a pharmaceutical carrier, and is not even mentioned as a prebiotic. (See, e.g., *Reid et al.*'s brief discussion of prebiotics in paragraph 44). Moreover, the Examiner has provided no evidence that agar is a mucopolysaccharide and agar is defined as a "polysaccharide" (see Exhibit 1, hereto), which is identified as a prior art prebiotic on page 5, l. 18 of the present application. Therefore, agar is not a mucopolysaccharide and the rejection under 35 U.S.C. § 102 is respectfully traversed.

II. Rejection of Claims 18-21 Under §112.

The Examiner has rejected claims 18-21 under 35 U.S.C. § 112 ¶ 1 as not being enabled and essentially takes the position that the invention is limited to the preferred embodiments of delivering a composition according to the invention via different tubes (such as nasogastrointestinal or a percutaneous endoscopic technique). Applicant traverses this position because the Examiner has not provided objective reasoning as to why one skilled in the art could not make and use the claimed invention without undue experimentation.

a. The Examiner Has Failed to Provide Evidence to Rebut the Presumption that the Specification is Enabling.

There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is "undue." These factors include, but are not limited to:

(A) The breadth of the claims;
(B) The nature of the invention;
(C) The state of the prior art;
(D) The level of one of ordinary skill;
(E) The level of predictability in the art;
(F) The amount of direction provided by the inventor;
(G) The existence of working examples; and
(H) The quantity of experimentation needed to make or use the invention based on the content of the disclosure.

MPEP § 2164.01(a); In re Wands, 858 F.2d 731, 737, 8 UPSQ2d 1400, 1404 (Fed.Cir. 1988) (reversing the PTO's determination that claims directed to methods for detection of hepatitis B surface antigens did not satisfy the enablement requirement).

The Examiner's only argument for finding that the specification is not enabling is apparently that, although the specification lists several techniques for delivering a composition according to the invention to a position downstream of the stomach, it does not specifically disclose every conceivable way of performing this function. This statement by the Examiner is not the objective, technical reasoning sufficient to establish a rejection for lack of enablement under 35 U.S.C. § 112 ¶ 1. The Examiner has not considered at least the nature of the invention, the state of the prior art, the level of skill in the art, or the level of predictability of the art. Moreover, none of the factors under MPEP § 2164.01(a) appear to have been addressed in the Office Action. Thus, the Examiner has not established an objective basis to reject the claims for lack of enablement under 35 U.S.C. § 112 ¶ 1 or to limit the claims to the preferred embodiments. The rejection under 35 U.S.C. § 112 ¶ 1 should be traversed for this reason alone.

b. The Claims Are Not Limited to the Preferred Embodiments.

First, as a matter of law patents are generally not limited to the preferred embodiments unless explicitly stated in the specification. The present specification contains no statements or teachings limiting the invention to the preferred embodiments. Second, the specification at pages 16-18 teaches several ways to deliver a composition according to the invention to a position downstream of the stomach, and one could follow these teachings and develop alternate delivery techniques falling within the scope of claims 18-21 without undue experimentation. See United States v. Telectronics, Inc., 857 F.2d 778, 785, 8 USPQ2d 1217, 1223 (Fed. Cir. 1988) ("The test of enablement is whether one reasonably skilled in the art could make or use the invention from the disclosures in the patent coupled with information known in the art without undue experimentation.").

A patent specification does not have to explicitly "teach" someone how to determine if a particular product falls within the claimed scope of the invention. As long as the specification discloses at least one method for making and using the claimed invention **that bears a reasonable correlation to the entire scope of the claim**, then the enablement requirement of 35 U.S.C. § 112, paragraph 1 is satisfied. In this case, those skilled in the art would know how to make the invention utilizing a suitable delivery technique without undue experimentation, and the Examiner has provided no objective reasoning to the contrary. In re Fisher, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970) (Failure to disclose other methods by which the claimed invention may be made does not render a claim invalid under 35 U.S.C. 112): Spectra-Physics, Inc. v. Coherent, Inc., 837 F.2d 1524, 1533, 3 USPQ2d 1737, 1743 (Fed. Cir.), cert. denied, 484 U.S. 954 (1987).

Third, the present inventions, directed to methods for delivering a composition into the gastrointestinal tract of a human, downstream of the stomach, are in a fairly predictable art field. One skilled in the art, given the examples in the specification, would discover through simple trial and error the methods that would and would not work in the invention. In re Colianni, 561 F.2d 220, 224, 195 USPQ 150, 153 (CCPA 1977) (Even "an extended period of experimentation may not be undue if the skilled artisan is given sufficient direction or guidance."); In re Wands, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988) ("The test is not merely quantitative, since a considerable amount of experimentation is permissible, if it is merely routine, or if the specification in question provides a reasonable amount of guidance with respect to the direction in which the experimentation should proceed.") (citing In re Angstadt, 537 F.2d 489, 502-04, 190 USPQ 214, 217-19 (CCPA 1976)). Moreover, even in unpredictable arts, a disclosure of every operable species is not required. A single embodiment may provide broad enablement in cases involving predictable factors, such as mechanical or electrical elements. In re Vickers, 141 F.2d 522, 526-27, 61 USPQ 122, 127 (CCPA 1944); In re Cook, 439 F.2d 730, 734, 169 USPQ 298, 301 (CCPA 1971).

CONCLUSION.

In view of the amendments and arguments herein, this Application is believed to be in condition for allowance and favorable action is requested. Applicant reserves the right to prosecute additional claims, including claims of broader scope, in a continuation or a divisional application.

Applicant hereby petitions for any extension of time which may be required to maintain the pendency of this case, and any required fee, except for the Issue Fee, for such extension is to be charged to **Deposit Account No. 19-3878**.

The Examiner is invited to telephone the undersigned at the telephone number listed below if it would in any way advance prosecution of this case.

Respectfully submitted,

June 29, 2004
Date

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